

Arguments/Remarks

As of the Office action mailed August 27, 2003, claims 1-10 are pending with claims 1-7 standing rejected and claims 8-10 withdrawn from consideration. Reexamination and reconsideration of the application as amended and in view of the remarks herein is respectfully requested.

Election

Applicant hereby affirms the earlier provisional election, without traverse, to prosecute the invention of Group I, including claims 1-7.

Priority Claim

The specification has been amended herein to include a cross-reference U.S. provisional application Serial No. 60/199,714, filed April 26, 2000, the benefit of which application is was claimed in the Declaration filed on July 24, 2001, and recognized on the Filing Receipt June 19, 2001.

Objections to the Drawings

The drawings have been objected to under 37 C.F.R. §1.83(a) as failing to show every claimed feature of the invention. Regarding the titanium insert recited in claim 4, Applicant directs the Examiner's attention to, e.g., to the features indicated by reference numerals 16a, 16b, and 16c, shown in FIGS. 1-3 and 5. Page 9, lines 6-7 of the disclosure teaches "the bottom portions 16a, 16b and 16c thereof, include a metallic, titanium, stainless steel, for example, or ceramic insert." Applicant therefore submits that this feature is shown in the drawings.

Regarding the recitation of claim 7, "said ports are connected together to a manifold to provide a single inlet/outlet", Applicant directs the Examiner's attention to FIG. 5. FIG. 5 illustrates an exemplary embodiment wherein the passageways 19a-c of the several ports "connect to a single outlet tube 2, which delivers fluid out of the chambers". Page 8, l. 21-22. FIG. 5 appears to illustrate a passage extending the length of the multiple port access device and in communication with each of the fluid chamber. It is, therefore, believed that this feature is adequately shown. Furthermore, those having skill in the art posses a sufficient understanding of a manifold that such a feature is readily understood.

Objections to the Specification

The specification has been objected for the reason that there is no support for the units of the durometer in the specification. Applicant submits that it is well understood by those having skill in the art that durometer refers to hardness of a material on the Shore scale. The Shore A scale is used for indicating the hardness of flexible or elastomeric materials, while the Shore D scale is used to indicate the hardness of rigid or hard materials. See, e.g., Glanvill, A. B., Plastics Engineer's Data Book, pg. 194-195 (American Edition, 1974). The application describes the septum as "constructed of silicone or similar elastomeric material". Page 8, l. 10-11. By this description, as well as the purpose to be served by the septum, i.e., to seal the chambers of the access device, but allow the penetration of needles, etc., therethrough and operate in a self sealing manner upon penetration by a needle, etc., and upon withdrawal thereof, the material of the septum is clearly a flexible or elastomeric material, the durometer of which would be properly indicated only on the Shore A scale, not the Shore D scale.

The specification has been amended on page 8, line 11 to recite --the septum can have a durometer ranging from 30 and 55 on the Shore A scale, since it is understood that the septum must withstand several large-diameter insertions while still maintaining fully sealed integrity--. Considering a person of ordinary skill in the art would understand that the Shore A scale is the only appropriate durometer scale for denoting the hardness of a material as described in the specification, no new matter is, therefore, believed entered by this amendment.

The specification has been objected to under 37 C.F.R. 1.75(d)(1) as failing to provide support for “a titanium insert covering at least a portion of said bottom portion of said port” recited in claim 4. Applicant directs the Examiner’s attention to page 9, lines 6-9 of the disclosure teaches “the bottom portions 16a, 16b and 16c thereof, include a metallic, titanium, stainless tell, for example, or ceramic insert. The insert at the bottom portions, 16a, 16b and 16c are molded, pressed, welded, bonded or attached by other known means”. Applicant therefore submits that the specification contains adequate support for the claimed titanium insert.

Rejections Under 35 U.S.C. §112

Claims 2 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because it is unclear what “between 30 and 55” is intending to claim. In pertinent part, claim 2 reads “said septum comprises a material having a durometer between 30 and 55.” It is well understood by those having skill in the art that durometer refers to hardness of a material on the Shore scale. The Shore A scale is used for indicating the hardness of flexible or elastomeric materials, while the Shore D scale is used to indicate the hardness of more rigid or hard materials. See, e.g., Glanvill, A. B., Plastics Engineer’s Data Book, pg. 194-195 (American

Edition, 1974). The application describes the septum as "constructed of silicone or similar elastomeric material". Page 8, l. 10-11. By this description, as well as the purpose to be served by the septum, i.e., to seal the chambers of the access device, but allow the penetration of needles, etc., therethrough and operate in a self sealing manner upon penetration by a needle, etc., and upon withdrawal thereof, it would be readily understood by a person of ordinary skill in the art that the septum as described in the application is made of a material, the durometer of which would be properly indicated only on the Shore A scale, not the Shore D scale.

Claim 2 has been amended to recite --said septum having a durometer between 30 and 55 on the Shore A scale--. Considering a person of ordinary skill in the art would understand that the Shore A scale is the only appropriate durometer scale for denoting the hardness of a material as described in the specification, no new matter is, therefore, believed entered by this amendment.

Claim 7 has also been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because "said ports" lacks proper antecedent basis. The use of the term "ports" appears to have been a clerical error. Claim 7 has been amended to replace "said ports" with --said chambers-- in both lines 1 and 2 of the claim. Independent claim 1 recites "a housing defining a plurality of interconnected chambers". Accordingly, all elements of claim 7 now appear to possess proper antecedent basis.

Rejections Under 35 U.S.C. §102

Claim 1, and 3-7 have been rejected under 35 U.S.C. §102(b) as being anticipated by Powers et al. (U.S. Patent No. 5,833,654). Applicant respectfully submits that Powers et al. does

not teach all of the elements of the claimed invention, and, therefore, does not anticipate claims 1 and 3-7.

In rejecting these claims the Examiner asserts “[t]he spring mechanism [of Powers et al.] is the pressure that the walls are applying force to the septum.” Without conceding that the walls of Powers et al. perform the same function as the spring mechanism of the instant invention, whether or not a cited reference discloses achieving the same result using a different apparatus is irrelevant. In order to anticipate a claim, the reference must teach every element of the claim.

Independent claim 1, from which claims 3-7 depend, recites, in part, “a spring mechanism disposed between said sidewalls and said septum and applying an inward force on said septum.” That is, independent claim 1 does not simply require “applying an inward force on said septum”, but rather a discrete “spring mechanism” applying an inward force on the septum. The claimed spring mechanism is in addition to the sidewall portion recited in line 3 of claim 1. The separate element of a spring mechanism is not taught or suggested by Powers et al. The Examiner even admits this deficiency. In stead of asserting that Powers et al. includes the required element, the Examiner instead alleges that the function of the spring element is performed by the sidewalls of Powers et al.

In view of the above, it is clear that Powers et al. does not teach, or suggest, the claimed “spring mechanism disposed between said sidewalls and said septum”. This reference is, therefore, inadequate to anticipate independent claim 1, or claims 3-7 depending therefrom. Applicant respectfully requests that the rejection of claims 1 and 3-7 be withdrawn upon reconsideration.

Rejections Under 35 U.S.C. §103

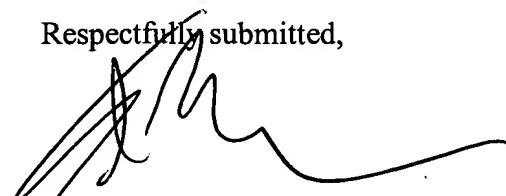
Claim 2 has been rejected under 35 U.S.C. §103(a) as being obvious over Powers et al. in view of Eliasen et al (U.S. Patent No. 6,213,973). The additional teachings of Eliasen et al. do not remedy the deficiencies of the primary reference. Therefore, Applicant submits that the claimed invention is not taught or suggested by the cited references.

As discussed with respect to the rejection of independent claim 1, from which claim 2 depends, Powers et al. fails to identify the separate element of a spring mechanism consistent with the claim. This limitation is incorporated by reference into claim 2. While Eliasen et al. does appear to teach a septum having a durometer within the claimed range, Eliasen et al. does not teach a "spring mechanism disposed between said sidewalls and said septum and applying an inward force on said septum." Accordingly, the combined teachings of Powers et al. and Eliasen et al. do not teach or suggest every element of claim 2. It is respectfully requested that the rejection of claim 2 be withdrawn upon reconsideration.

In view of the foregoing, all of the outstanding objections and rejection are believed overcome. The application is therefore in condition for allowance. Early and favorable action is respectfully solicited.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 50-2121.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450 on September 24, 2003, at Manchester, New Hampshire.

By April Davis